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December 16, 1999

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 99D-4396; Draft Guidance for Industry on Financial Disclosure by Clinical Investigators, 64 *Federal Resister 57640 (October 26, 1999)*

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, beauty care, nutritionals and medical devices. We are a leading company in the development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders and oncology.

The Bristol-Myers Squibb Pharmaceutical Research Institute (PRI) is a global research and development organization that employs more than 4,300 scientists worldwide. PRI scientists are dedicated to discovering and developing best in class, innovative, therapeutic and preventive agents, with a focus on ten therapeutic areas of significant medical need. Currently, the PRI pipeline comprises more than 50 compounds under active development. In 1998, pharmaceutical research and development spending totaled $1.4 billion.

For these reasons, we are very interested in and well qualified to comment on this FDA proposal to issue a guidance for industry regarding financial disclosure by clinical investigators.

Summary of BMS Comments on Proposal

We commend the U.S. FDA for attempting to provide a guidance document for the recently issued financial disclosure regulations.
However, there are several aspects of the proposed guidance that appear contrary to the FDA's stated objectives or require further clarification, which we have cited below.

Specific Comments (Items that Need Clarification & Recommended Actions)

I. Elements Which Should Be Modified

A. Section IV, Question 3

The answer to Question 3 only refers to "the chief financial officer" as an example of a corporate official who can assume responsibility for the signing of financial certification/disclosure forms, creating the erroneous impression that only the chief

financial officer of a corporation is authorized to sign such forms. The answer should make clear that any responsible corporate official or representative can sign the financial certification/disclosure forms.

Recommendation:
The answer to Question 3 should be modified to make clear that a corporation is free to authorize any responsible corporate official or representative to sign its financial certification/disclosure forms. The answer should also be modified to give additional examples of individuals who can do so, such as the head of clinical research and development or the head of regulatory affairs.

B. Section IV, Question 7

The answer to Question 7 refers to a number of circumstances under which an Investigator must disclose financial interests relating to a CRO. However, the answer ignores the typical situation in which a sponsor provides all material support for a covered study and a CRO simply conducts the covered clinical study for the sponsor or otherwise assumes some responsibilities of the sponsor for the covered clinical study.

Recommendation:
The answer to Question 7 should be modified to clarify that under the circumstances discussed above, the Investigator does not have to report financial interests relating to the CRO.

C. Section IV, Question 9

The answer to Question 9 indicates that an applicant does not need to submit new financial information to the FDA after submission of an application for regulatory approval. However, FDA does not set a cut-off date before an application is filed after which such financial information need not be submitted. This will make it impossible for an applicant to complete an application for regulatory approval.

Recommendation:
FDA should establish a period of time prior to submission of a regulatory filing after which financial information received by an applicant need not be submitted to FDA. A time period of 120 days seems reasonable and will give applicants sufficient time to compile financial information for a regulatory filing.

D. Section IV, Question 12

The answer to Question 12 is not clear regarding whether completion of a study refers to the overall clinical trial or completion of the study at a particular study site. It is our understanding that for purposes of these regulations, completion of a study refers to completion of the study at a particular study site.

Recommendation:
In line 1 of the answer to Question 12, the words “at a site” should be inserted after the words “all study subjects”.

E. Section IV, Question 13

In line 4 of the answer to Question 13, a reference is made to particular records that sponsors/applicants must keep on file without specifying the nature of those records. However, the types of records that should be retained are more specifically described in the answer to Question 28.

Recommendation:
In line 4 of the answer to Question 13, the words “as described in Question 28” should be added after the words “must keep records”.

F. Section IV, Question 23

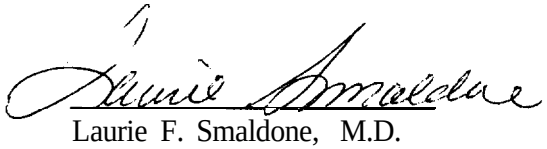
In the answer to Question 23, the word “equipment” is used in the fourth sentence, while a specific type of equipment, “computer software” is referenced in the fifth sentence. It is assumed that FDA did not intend the type of equipment that may be supplied for a particular clinical trial and therefore is not subject to financial disclosure to be limited to computer software.

Recommendation:
In the fifth sentence, the words “computer software” and “software” should be replaced with the word “equipment”.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

BRISTOL-MYERS SQUIBB
PHARMACEUTICAL RESEARCH INSTITUTE



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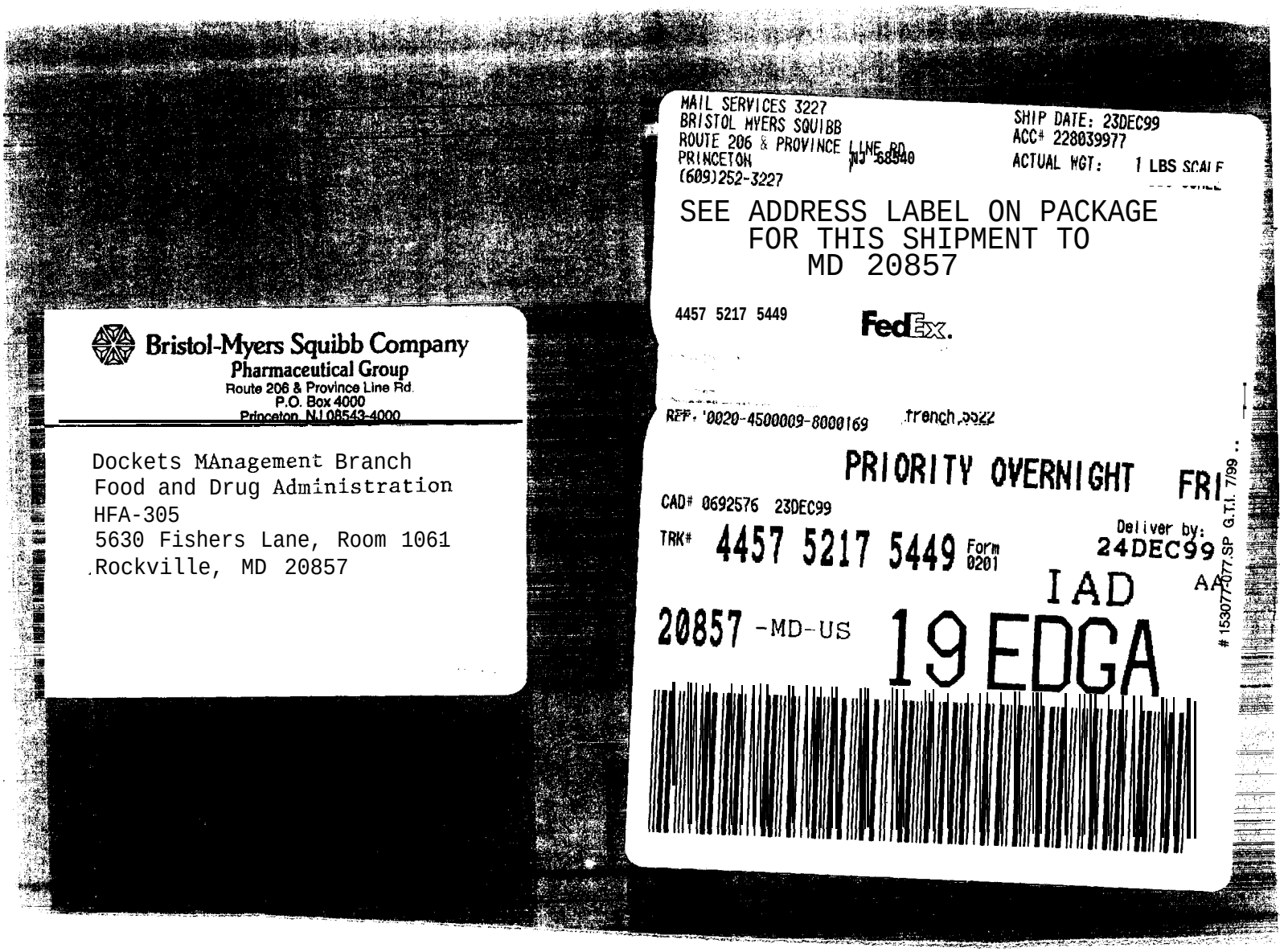

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